SAME SIZE ARTWORK
LEAFLET SIZE : 264 mm x 186 mm

22 mm

24 mm

SPACE FOR PHARMACODE

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For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Altacef® - 250 / 500 mg

FILM COATED TABLET

Cefuroxime Axetil USP 250/500 mg

Composition
Each film coated tablet contains: 250 mg
Cefuroxime as Cefuroxime axetil USP
Colour Titanium Dioxide BP

Each film coated tablet contains: 500 mg
Cefuroxime as Cefuroxime axetil USP
Colour Titanium Dioxide BP

PHARMACEUTICAL FORM
Film Coated Tablet

CLINICAL PARTICULARS

Therapeutic indications
ALTACEF FILM COATED TABLET is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime, which is resistant to most β (beta)-lactamases and is active against a wide range of Gram-positive and Gram-negative organisms.

ALTACEF FILM COATED TABLET are indicated for the treatment of the infections caused by susceptible bacteria. Susceptibility to ALTACEF FILM COATED TABLET will vary with geography and time and local susceptibility data should be consulted where available.

Indications include:
- upper respiratory tract infections for example, ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis
- lower respiratory tract infections for example, pneumonia, acute bronchitis, and acute exacerbations of chronic bronchitis
- genito-urinary tract infections for example, pyelonephritis, cystitis and urethritis
- skin and soft tissue infections for example, furunculosis, pyoderma and impetigo
- gonorrhoea, acute uncomplicated gonococcal urethritis, and cervicitis

Cefuroxime is also available as the sodium salt for parenteral administration.

This permits the use of sequential therapy with the same antibiotic, when a change from parenteral to oral therapy is clinically indicated.

Where appropriate ALTACEF FILM COATED TABLET is effective when used following initial parenteral (cefuroxime sodium) in the treatment of pneumonia and acute exacerbations of chronic bronchitis.

Posology and Method of Administration

Posology

The usual course of therapy is seven days (range 5 to 10 days).

ALTACEF FILM COATED TABLET should be taken after food for optimum absorption.

- Adults

Most infections	250 mg twice daily
Urinary tract infections	250 mg twice daily
Mild to moderate lower respiratory tract infections e.g. bronchitis	250 mg twice daily
More severe lower respiratory tract infections, or if pneumonia is suspected	500 mg twice daily
Pyelonephritis	250 mg twice daily
Uncomplicated gonorrhoea	single dose of 1 g

Sequential therapy

Pneumonia
1.5 g cefuroxime sodium twice daily (given i.v. or i.m.) for 48 to 72 hours, followed by 500 mg twice daily *ALTACEF FILM COATED TABLET* oral therapy for 7 to 10 days.

Acute exacerbations of chronic bronchitis
750 mg cefuroxime sodium twice daily (given i.v. or i.m.) for 48 to 72 hours, followed by 500 mg twice daily *ALTACEF FILM COATED TABLET* oral therapy for 5 to 10 days.

Duration of both parenteral and oral therapy is determined by the severity of the infection and the clinical status of the patient.

- Children

Most infections	125 mg (1 x 125 mg tablet) twice daily
Children with otitis media or, where appropriate, with more severe infections	250 mg (1 x 250 mg tablet or 2 x 125 mg tablet) twice daily

ALTACEF FILM COATED TABLET should not be crushed or split and are therefore unsuitable for treatment of patients, such as younger children, who cannot swallow whole tablet.

There is no experience of using ALTACEF FILM COATED TABLET in children under the age of 3 months.

- **Renal impairment**

Cefuroxime is primarily excreted by kidneys. In patients with markedly impaired renal function it is recommended that the dosage of cefuroxime be reduced to compensate for its slower excretion (see the table below).

Creatinine Clearance	$T_{½}$ (hours)	Recommended Dosage
≥30 ml/min	1.4 - 2.4	No dose adjustment necessary standard dose of 125 mg to 500 mg given twice daily
10-29 ml/min	4.6	Standard individual dose given every 24 hours
<10 ml/min	16.8	Standard individual dose given every 48 hours
During haemodialysis	2 – 4	A single additional standard individual dose should be given at the end of each dialysis

Contraindications
Hypersensitivity to cefuroxime or any of the excipients as in list of Excipients Patients with known hypersensitivity to cephalosporin antibiotics.

History of severe hypersensitivity (e.g. anaphylactic reaction) to any other type of betalactam antibacterial agent (penicillins, monobactams and carbapenems).

Special Warnings and Precautions for Use

Hypersensitivity reactions
Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with Altacef film coated Tablet careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Altacef film coated Tablet must be discontinued immediately and appropriate alternative therapy instituted.

Special care is indicated in patients who have experienced an allergic reaction to penicillins or other beta-lactams.

As with other antibiotics, use of cefuroxime axetil may result in the overgrowth of *Candida*. Prolonged use may also result in the overgrowth of other non-susceptible microorganisms (e.g. enterococci and *Clostridium difficile*), which may require interruption of treatment.

Pseudomembranous colitis has been reported with the use of antibiotics, and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

With a sequential therapy regime the timing of change to oral therapy is determined by severity of the infection, clinical status of the patient and susceptibility of the pathogens involved. If there is no clinical improvement within 72 hours, then the parenteral course of treatment must be continued.

Please refer to the relevant prescribing information for cefuroxime sodium before initiating sequential therapy.

Interaction with other medicinal products and other forms of interaction
Drugs which reduce gastric acidity may result in a lower bioavailability of cefuroxime axetil compared with that of the fasting state and tend to cancel the effect of enhanced post-prandial absorption.

In common with other antibiotics, cefuroxime axetil may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

As a false negative result may occur in the ferricyanide test, it is recommended that either the glucose oxidase or hexokinase methods are used to determine blood/plasma glucose levels in patients receiving cefuroxime axetil. This antibiotic does not interfere in the alkaline picrate assay for creatinine.

Fertility, Pregnancy and lactation
There is no experimental evidence of embryopathic or teratogenic effects attributable to cefuroxime axetil but, as with all drugs, it should be administered with caution during the early months of pregnancy. Cefuroxime is excreted in human milk, and consequently caution should be exercised when cefuroxime axetil is administered to a nursing mother.

Effects on ability to drive and use machines
No studies on the effects on the ability to drive and use machines have been performed. However, as this medicine may cause dizziness, patients should be warned to be cautious when driving or operating machinery.

Undesirable effects
Adverse drug reactions to cefuroxime axetil are generally mild and transient in nature.

The frequency categories assigned to the adverse reactions below are estimates, as for most reactions suitable data for calculating incidence were not available. In addition the incidence of adverse reactions associated with cefuroxime axetil may vary according to the indication.

The following convention has been used for the classification of frequency:
Very common
Common
Uncommon
Rare
Very rare

Infections and infestations
Common: Overgrowth of Candida

Blood and lymphatic system disorders
Common: Eosinophilia
Uncommon: Positive Coombs' test, thrombocytopenia, leukopenia (sometimes profound)
Very rare: Haemolytic anaemia

Cephalosporins as a class tend to be absorbed onto the surface of red cells membranes and react with antibodies directed against the drug to produce a positive Coombs' test (which can interfere with cross-matching of blood) and very rarely haemolytic anaemia.

Immune system disorders
Hypersensitivity reactions including
Uncommon: Skin rashes
Rare: Urticaria, pruritus
Very rare: Drug fever, serum sickness, anaphylaxis

Nervous system disorders
Common: Headache, dizziness

Gastrointestinal disorders
Common: Gastrointestinal disturbances including diarrhoea, nausea, abdominal pain
Uncommon: Vomiting
Rare: Pseudomembranous colitis

PE00000 **MY**

ICONGRAPHICS CODE:

PANTONE SHADE

PANTONE BLACK PROCESS C

Supersedes Artwork Code

PHARMACODE:

SAME SIZE ARTWORK
LEAFLET SIZE : 264 mm x 186 mm

Hepatobiliary disorders
Common: Transient increases of hepatic enzyme levels, [ALT (SGPT), AST (SGOT), LDH]
Very rare: Jaundice (predominantly cholestatic), hepatitis

Skin and subcutaneous tissue disorders
Very rare: Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (exanthematic necrolysis)

See also Immune system disorders.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important.It allows continued monitoring of the benefit/risk balance of the medicinal product.

Overdose
Overdose can lead to neurological sequelae including encephalopathy, convulsions and coma. Symptoms of overdose can occur if the dose is not reduced appropriately in patients with renal impairment.

Serum levels of cefuroxime can be reduced by haemodialysis and peritoneal dialysis.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties
The prevalence of acquired resistance is geographically and time dependent and for select species may be very high. Local information on resistance is desirable, particularly when treating severe infections.

In vitro susceptibility of micro-organisms to Cefuroxime
Commonly susceptible species
Gram-Positive Aerobes: *Staphylococcus aureus* (methicillin susceptible) *Coagulase negative staphylococcus (methicillin susceptible)* *Streptococcus pyogenes* Beta-hemolytic streptococci
Gram-Negative Aerobes: *Haemophilus influenza* including ampicillin resistant strains *Haemophilus parainfluenzae** *Moraxella catarrhalis* *Neisseria gonorrhoea** including penicillinase and non-penicillinase producing strains
Gram-Positive Anaerobes : *Peptostreptococcus* spp. *Propionibacterium* spp.
Spirochaetes: *Borrelia burgdorferi*
Microorganisms for which acquired resistance may be a problem
Gram-Positive Aerobes: *Streptococcus pneumoniae*
Gram-Negative Aerobes: *Citrobacter* spp. not including *C. freundii* *Enterobacter* spp. not including *E. aerogenes and E.cloacae* *Escherichia coli* *Klebsiella* spp. including Klebsiella pneumonia *Proteus mirabilis* *Proteus* spp. not including *P. penneri* and *P. vulgaris* *Providencia* spp.
Gram-Positive Anaerobes: *Clostridium* spp. not including *C. difficile*
Gram-Negative Anaerobes: *Bacteroides spp.* not including *B. fragilis* *Fusobacterium spp.*
Inherently resistant organisms
Gram-Positive Aerobes: *Enterococcus* spp. including *E. faecalis* and *E. faecium* *Listeria* monocytogenes
Gram-Negative Aerobes: *Acinetobacter* spp. *Burkholderia cepacia* *Campylobacter* spp. *Citrobacter freundii* *Enterobacter aerogenes* *Enterobacter cloacae* *Morganella morganii* *Proteus penneri* *Proteus vulgaris* *Pseudomonas* spp. including *Pseudomonas aeruginosa* *Serratia* spp. Stenotrophomonas *maltophilia*
Gram-Positive Anaerobes: *Clostridium difficile*
Gram-Negative Anaerobes: *Bacteroides fragilis*
Others: *Chlamydia species* *Mycoplasma species* *Legionella species*

Pharmacokinetic properties

Absorption
After oral administration cefuroxime axetil is slowly absorbed from the gastrointestinal tract and rapidly hydrolysed in the intestinal mucosa and blood to release cefuroxime into the circulation.

Optimum absorption occurs when it is administered shortly after a meal.

Following administration of ALTACEF FILM COATED TABLET peak serum levels (2.1 mg/l for a 125 mg dose, 4.1 mg/l for a 250 mg dose, 7.0 mg/l for a 500 mg dose and 13.6 mg/l for a 1 g dose) occur approximately 2 to 3 hours after dosing when taken with food.

Distribution
Protein binding has been variously stated as 33 to 50% depending on the methodology used.

Biotransformation
Cefuroxime is not metabolised.

Elimination
The serum half-life is between 1 and 1.5 hours.

Cefuroxime is excreted by glomerular filtration and tubular secretion. Concurrent administration of probenecid increases the area under the mean serum concentrations time curve by 50%.

Renal impairment:
Cefuroxime pharmacokinetics have been investigated in patients with various degrees of renal impairment. Cefuroxime elimination half-life increases with decrease in renal function which serves as the basis for dosage adjustment recommendations in this group of patients. In patients undergoing haemodialysis, at least 60% of the total amount of cefuroxime present in the body at the start of dialysis will be removed during a 4-hour dialysis period. Therefore, an additional single dose of cefuroxime should be administered following the completion of haemodialysis.

PHARMACEUTICAL PARTICULARS

List of excipients
Microcrystalline cellulose
Colloidal Silicon Dioxide
Hydrogenated Castor Oil
Croscarmellose sodium,
Sodium lauryl sulphate
Hypromellose, 3cps
Hypromellose, 15cps
Purified Talc
Titanium Dioxide
Propylene glycol
Isopropyl Alcohol
Dichloromethane

Incompatibilities
A positive Coombs' test has been reported during treatment with cephalosporins - this phenomenon can interfere with cross-matching of blood.

Shelf life
36 months in a Alu-Alu blister pack and/or Alu-Alu Strip pack.

Special precautions for storage
ALTACEF FILM COATED TABLET in foil strips or blisters should be stored below 30°C.

Product Description:
250mg: White coloured, capsule shaped, film coated tablet debossed '250' on one side & plain on other side.
500mg: White coloured, capsule shaped, film coated tablet debossed '500' on one side & plain on other side.

Nature and contents of container

Product	Packaging Configuration
Cefuroxime Axetil USP 250 mg	10 tablet in a Alu-Alu blister pack and/or Alu-Alu Strip pack, 5 such blisters/Strips packed in carton
Cefuroxime Axetil USP 500 mg	10 tablet in a Alu-Alu blister pack and/or Alu-Alu Strip pack, 5 such blisters/Strips packed in carton

PRESENTATION
5 x 10's

DATE OF REVISION OF THE TEXT
September 2026

Product Registration Holder:
Glenmark Pharmaceuticals (Malaysia)
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® Registered Trade Mark

PE00000 MY

ICONGRAPHICS CODE:

PANTONE SHADE

PANTONE BLACK PROCESS C

Supersedes Artwork Code

PHARMACODE: